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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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R. Danny Huntington
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,241		
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-23,25 and 27* is/are pending in the application.

4a) Of the above claim(s) *21 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-20,22,25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment filed 12/31/03. Claims 2-23, 25 and 27 are pending.

RESPONSE TO APPLICANT'S DETERMINATION OF ERROR

Applicants at paragraph 3 of page 6 of the remarks filed 12/31/03 cited that withdrawal of claims 21 and 23 from examination is in error. It is respectfully noted that applicants elected with traverse glioblastomas specific tumor and 5-fluorouracil (5-FU) anticancer agent; the search was extended to carboplatin anticancer agent; thus claims 1-20, 22 and 24-27 read on the elected species and claims 21 and 23 are appropriately withdrawn from examination. It is however correct that upon the allowance of generic claim applicants will be entitled to consideration of claims to additional species. No generic claim was found allowable in the previous office action. It was and is correct to withdraw claims 21 and 23 from consideration and applicants are entitled to a consideration of claims to additional species upon the allowance of the generic claim.

Claim Rejections - 35 USC § 112

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 contains the trademark/trade name POLYSORBATE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Amendment to claim 14 leaves the trademark/trade name in the claim in lower case letter. Thus the amendment does not overcome the rejection of claim 14 over the use of the trademark/ trade name.

3. Applicants' arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

4. The objection of claim 18 as being dependent on a rejected base claim and the indication that claim 18 would be allowable if rewritten in independent form including al the limitations of the base claim is withdrawn in view of the rejection below. Rejections including claim 18 follow:

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 2-7, 9-15, 17-20, 22, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emerich et al. ("Injectable Chemotherapeutic Microspheres and Glioma II: Enhance Survival Following Implantation Into Deep Inoperable Tumors," Pharmaceutical Research, Vol. 17, no. 7, 2000, pages 776-781) in view of Kubo et al. ("Treatment of malignant brain tumor with slowly releasing anticancer drug-polymer composites," International Journal of Radiation Applications and Instrumentation. Part C. Radiation Physics and Chemistry, Vo. 39, issue 6, June 1992, pp 521-525).

Emerich discloses chemotherapeutic implantable, biodegradable polymer comprising carboplatin or BCNU for treating glioma and the carboplatin-loaded microspheres are injected into the center of the tumor (abstract). The microspheres are stereotactically injected into the tumors and the implantable biodegradable carboplatin loaded microsphere composition contains 0.9% saline, 0.1% TWEEN and 3% carboxymethylcellulose and the composition has a low viscosity (page 777). The biodegradable polymer inherently delays the release of the carboplatin. Administration of the carboplatin-loaded microsphere into the tumor would inherently maintain an effective concentration for a period of time including up to at least three weeks. In the absence of a showing of criticality, amounts of viscosity modifier and isotonicity agent and mg amount of biodegradable microspheres do not patentably distinguish the instant claims over the prior art that teaches the respective composition for treating glioma. While Emerich discloses using rat glioma as the test case study and does not specifically disclose administering drug loaded microsphere to human tumor, it is common practice to study therapeutic effects of drugs or chemotherapy in lower animal model for transference to the human larger animal model. Emerich uses a rat model to study release of the carboplatin into

the tumor and studies are generally done in small animal model before clinical trials and use in the bigger animal model such as the human.

However, while Emerich discloses treating glioma with the carboplatin-loaded microsphere, Emerich differs from the instant claims by not teaching radiotherapy treatment after the administration/implantation/injection of the carboplatin-loaded microsphere to the tumor. But, Kubo discloses radiotherapy treatment after implantation of slowly releasing anticancer drug compositions that contain 5-FU (abstract). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to test an optimized composition of the prior art in the rat small animal model according to the disclosure of Emerich. One having ordinary skill in the art would have been motivated to stereotactically administer the optimized composition of the prior art into a human suffering from glioma and follow the implantation with radiotherapy with the expectation that the release of the anticancer agent and administration of radiotherapy will act in synergy in the treatment of glioma.

7. Claims 2-9, 16-18, 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boisdstron-Celle et al. ("Preparation and Characterization of 5-Fluorouracil-loaded microparticles as Biodegradable Anticancer Drug Carriers," J. Pharm. Pharmacol. 1999, 47: 108-114) in view of Kubo et al. ("Treatment of malignant brain tumor with slowly releasing anticancer drug-polymer composites," International Journal of Radiation Applications and Instrumentation. Part C. Radiation Physics and Chemistry, Vo. 39, issue 6, June 1992, pp 521-525).

Boisdstron-Celle discloses a controlled release device comprising biodegradable microspheres that comprise PLGA (50% lactic acid and 50% glycolic acid) polymer and 5-

fluorouracil in stable emulsion for stereotactic injection and 5-fluorouracil (5-FU) is used to treat common human glioblastoma, most common human glioma (abstract and pages 108-114). Regarding treating a human suffering from inoperable tumors, it is noted that Boisdstron-Celle uses in vitro analysis to test the release pattern of 5-FU loaded PLAGA microspheres. However, the aim of the study is to be able to stereotactically implant the 5-FU loaded microspheres in the brain to treat brain tumors such as glioblastoma, which is the most common human malignant glioma and thus for eventual transference of the study to human subject. It is common practice to study therapeutic effects of drugs or chemotherapy in vitro model for transference to the human or other animal model.

Boisdstron-Celle differs from the instant claims by failing to teach administration of radiotherapy after the injection of the 5-FU loaded microsphere in to the tumor. But, Kubo discloses radiotherapy treatment after implantation of slowly releasing anticancer drug compositions that contain 5-FU (abstract). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to test an optimized composition of the prior art in the in vitro model according to the disclosure of Boisdstron-Celle. One having ordinary skill in the art would have been motivated to stereotactically administer the composition of the prior art into a human suffering from glioma and follow the implantation with radiotherapy with the expectation the release of the anticancer agent and administration of radiotherapy will act in synergy in the treatment of glioblastoma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600